

CLAIMS

[00131] 1. A valve prosthesis device suitable for implantation in corporeal ducts, the device comprising:

[00132] a support stent, and

[00133] a valve assembly comprising a flexible conduit having an inlet end and an outlet end,

[00134] wherein when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position; wherein a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow; and where the device is configured so that retrograde flow will be altered from laminar flow and directed towards the leaflets to effect closing .

[00135] 2. The valve prosthesis device of Claim 1, wherein the support stent comprises a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location

[00136] 3. The valve prosthesis device of Claim 1, wherein the support stent is provided with a plurality of longitudinally rigid support beams of fixed length.

[00137] 4. The valve prosthesis device of Claim 1, wherein the valve assembly comprises pliant material attached to the support beams and provides collapsible slack portions of the conduit at the outlet.

[00138] 5. The valve prosthesis of Claim 1, wherein the device is configured so that an artificial sinus is formed adjacent to the valve assembly.

[00139] 6. The valve prosthesis of Claim 1, wherein the retrograde flow will be substantially non-laminar.

[00140] 7. A valve prosthesis device suitable for implantation in corporeal ducts, the device comprising:

[00141] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; and

[00142] a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

[00143] wherein when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, wherein a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow, and wherein the device is configured so that retrograde flow will be altered from laminar flow and directed towards the leaflets to effect closing ..

[00144] 8. The valve prosthesis device of Claim 7, wherein the support stent comprises an annular frame.

[00145] 9. The valve prosthesis device of Claim 7, wherein said valve assembly has a tricuspid configuration.

[00146] 10. The valve prosthesis device of Claim 7, wherein said valve assembly is made from biocompatible material.

[00147] 11. The valve prosthesis device of Claim 10, wherein the valve assembly is made from pericardial tissue, or other biological tissue.

[00148] 12. The valve prosthesis device of Claim 7, wherein said valve assembly is made from biocompatible polymers.

[00149] 13. The valve prosthesis device of Claim 12, wherein the valve assembly is made from materials selected from polyurethane and polyethylene terephthalate.

[00150] 14. The valve prosthesis device of Claim 13, wherein said valve assembly comprises a main body made from polyethylene terephthalate and leaflets made from polyurethane.

[00151] 15. The valve prosthesis device of Claim 7, wherein said support stent is made from nickel titanium.

[00152] 16. The valve prosthesis device of Claim 7, wherein the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

[00153] 17. The valve prosthesis device of Claim 7, wherein the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

[00154] 18. The valve prosthesis device of Claim 7, wherein the support beams are chemically adhered to the support stent.

[00155] 19. The valve prosthesis device of Claim 7, wherein said valve assembly is riveted to the support beams.

[00156] 20. The valve prosthesis device of Claim 7, wherein said valve assembly is stitched to the support beams.

[00157] 21. The valve prosthesis device of Claim 7, wherein said beams are manufactured by injection using a mold, or by machining.

[00158] 22. The valve prosthesis device of Claim 7, wherein said valve assembly is rolled over the support stent at the inlet.

[00159] 23. The valve prosthesis device of Claim 7, wherein said valve device is manufactured using forging or dipping techniques.

[00160] 24. The valve prosthesis device of Claim 7, wherein said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

[00161] 25. The valve prosthesis device of Claim 7, wherein said valve assembly is made from a coiled polymer, coated by a coating layer of the same polymer.

[00162] 26. The valve prosthesis device of Claim 25, wherein said polymer is polyurethane.

[00163] 27. The valve prosthesis device of Claim 7, wherein the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

[00164] 28. The valve prosthesis device of Claim 27, wherein the heavy metal markers are selected from the group consisting of gold, platinum-iridium, and tantalum.

[00165] 29. The valve prosthesis device of Claim 7, wherein the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

[00166] 30. The valve prosthesis device of Claim 29, wherein said radio-opaque material comprises gold thread.

[00167] 31. The valve prosthesis device of Claim 7, wherein the diameter of said support stent, when fully deployed is in the range of from about 19 to about 26 mm.

[00168] 32. The valve prosthesis device of Claim 7, wherein the diameter of said support stent may be expanded from about 4 to about 26 mm.

[00169] 33. The valve prosthesis device of Claim 7, wherein the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of U-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

[00170] 34. The valve prosthesis device of Claim 7, wherein the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

[00171] 35. The valve prosthesis device of Claim 7, wherein the main body of the valve assembly is made from coiled wire coated with a coating material.

[00172] 36. The valve prosthesis device of Claim 35, wherein the coiled wire and the coating material is made from polyurethane.

[00173] 37. The valve prosthesis device of Claim 7, wherein a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

[00174] 38. The valve prosthesis device of Claim 37, wherein the strengthening-wire is made from nickel titanium alloy.

[00175] 39. A valve prosthesis device suitable for implantation in corporeal ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terephthalate and collapsible leaflets are made from polyurethane and wherein the device is configured so that retrograde flow will be altered from laminar flow and directed towards the leaflets to effect closing.

[00176] 40. The valve prosthesis device of Claim 39, wherein support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

[00177] 41. The valve prosthesis device of Claim 39, wherein said support beams are chemically adhered to the main body.

[00178] 42. A valve prosthesis device suitable for implantation in corporeal ducts, the device comprising:

[00179] a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length;

[00180] a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet; and

[00181] substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally,

[00182] wherein the device is configured so that retrograde flow will be altered from laminar flow and directed towards the leaflets to effect closing .

[00183] 43. A valve prosthesis device suitable for implantation in corporeal ducts, the device comprising:

[00184] an expandable support frame, the support frame provided with a plurality of longitudinally rigid support beams of fixed length; and

[00185] a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

[00186] wherein when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, wherein a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow, and wherein the device is configured so that retrograde flow will be altered from laminar flow and directed towards the leaflets to effect closing .

[00187] 44. The valve prosthetic device of Claim 43, wherein the expandable support frame comprises a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the corporeal duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location.

[00188] 45. The valve prosthetic device of Claim 43, wherein the support beams have a U-shaped cross section.

[00189] 46. The valve prosthetic device of Claim 45, wherein a holder is used to secure the pliant material to the support beams.

[00190] 47. The valve prosthetic device of Claim 43, wherein the support frame comprises three segments that form a circular assembly when assembled.

[00191] 48. The valve prosthetic device of Claim 43, wherein the support beams point inwardly with respect to a central longitudinal axis of the device.

[00192] 49. The valve prosthetic device of Claim 47, wherein the support beams point outwardly with respect to a central longitudinal axis of the device.

[00193] 50. The valve prosthetic device of Claim 43, further provided with a restricting tapered housing, for housing it in a crimped state

[00194] 51. The valve prosthetic device of Claim 43, wherein hooks are provided to secure the device in position after it is deployed.

[00195] 52. The valve prosthetic device of Claim 43, wherein the support beams comprise longitudinal bars having a narrow slit used as the commissural attachment so that extensions the pliant material are tightly inserted through it.

[00196] 53. The valve prosthetic device of Claim 52, wherein the extensions of the pliant material are wrapped about rigid bars serving as anchorage means.

[00197] 54. The valve prosthetic device of Claim 53, wherein extensions of the pliant material are sutured to each other at the rigid bars.

[00198] 55. The valve prosthetic device of Claim 54, wherein a bottom portion of the pliant material is attached to the inlet.

[00199] 56. The valve prosthetic device of Claim 43, wherein the support beams are each provided with a rounded pole, forming a loop through which the pliant material is inserted.

[00200] 57. The valve prosthetic device of Claim 43, wherein the pliant material is provided with longitudinal bars attached to the pliant material at positions assigned for attachment to the support frame, in order to prevent localized stress from forming.

[00201] 58. The valve prosthetic device of Claim 43, further provided with longitudinal bars having protrusions that are inserted in bores in the pliant material, a sheet of PET and through bores provided on the support beams.

[00202] 59. The valve prosthetic device of Claim 43, wherein the pliant material is sutured leaving the slack portions free of sutures.

[00203] 60. The valve prosthetic device of Claim 43, wherein a connecting member with a split portion is used to connect leaflets of the pliant material to the support beams, the split connecting member compressing the pliant material in position.

[00204] 61. The valve prosthetic device of Claim 60, wherein a portion of the connecting member is perpendicular to the split portion.

[00205] 62. The valve prosthetic device of Claim 43, wherein the support frame is provided with metallic members coupled to the stent and rigid members are positioned on two opposite sides of the metallic member and held against each other, holding a portion of the pliant material between them, sutured, the metallic members wrapped with PET.

[00206] 63. The valve prosthetic device of Claim 3, wherein the device is further provided with spring to reduce wear of the pliant material.

[00207] 64. The valve prosthetic device of Claim 63, wherein the spring is provided with a spiral.

[00208] 65. The valve prosthetic device of Claim 63, wherein the spring is made from stainless steel.

[00209] 66. The valve prosthetic device of Claim 63, wherein the spring is attached to slots provided on the support frame.

[00210] 67. The valve prosthetic device of Claim 43, wherein the pliant material is sutured to the support frame forming pockets.

[00211] 68. The valve prosthetic device of Claim 67, wherein attachment bars are provided on the stent support at a portion of the stent close to the outlet, on which the pliant material is coupled to, and wherein the pliant material is attached circumferentially to the inlet, leaving slack pliant material.

[00212] 69. The valve prosthetic device of Claim 43, wherein the outlet is tapered with respect to the inlet.

[00213] 70. The valve prosthetic device of Claim 69, wherein the support frame at the outlet is wider in diameter than the pliant material forming the outlet.

[00214] 71. The valve prosthetic device of Claim 43, wherein the pliant material is reinforced using PET.

[00215] 72. The valve prosthetic device of Claim 43, wherein the support frame is a tube having an inner wall, having sinusoidal fold lines, wherein the pliant material is sutured to the inner wall of the tube along suture lines.

[00216] 73. The valve prosthetic device of Claim 72, wherein additional piece of PET is added below the suture lines.

[00217] 74. The valve prosthetic device of Claim 43, wherein the device is incorporated with an angioplasty balloon.

[00218] 75. The valve prosthetic device of Claim 74, wherein the balloon has a central longitudinal axis that runs along a flow path through the device, and a perimeter, the balloon comprising four inflatable portions, one portion located along a central axis and the other three located on the perimeter, the pliant material in the form of leaflets is distributed about the perimeter.